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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,281	12/22/2003	Anita Melikian	10709/63	4482

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BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
03/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,281	MELIKIAN ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,14,15,19-28,30-33 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,14,15,19-28,30-33 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Non-Final Office Action

Claims 1-7, 14, 15, 19-28, 30-33 and 35-38 are pending. No claim is allowed at this time. Amendments are entered.

Summary of this Office Action dated 2/28/2009

1. Continued Examination Under 37 CFR 1.114
2. Information Disclosure Statement
3. Copending Applications
4. Specification
5. 35 USC § 112 (1) Written Description Rejection
6. Double Patenting Rejection
7. Response to Remarks
8. Communication

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/22/08 has been entered.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112—Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-38 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reasons apply.
Claims are drawn to method of inhibiting the binding of chemokines I-TAC and/or SDF-1 to a CCXCKR2 receptor, comprising contacting the composition of claim 33 with a cell that expresses the CCXCKR2 receptor for a time sufficient to inhibit the binding of the chemokines to the CCXCKR2 receptor (Claim 35) and method

of inhibiting the binding of chemokines I-TAC and/or SDF-1 to a CCXCKR2 receptor, comprising contacting the modulator of claim 1 (claim 36).

2. A method of treating cancer, comprising administering a therapeutically effective amount of the composition of claim .33 to a cancer patient for a time sufficient to treat the cancer (Claim 37) and a method of treating cancer, comprising administering a therapeutically effective amount of the modulator of claim 1 to a cancer patient for a time sufficient to treat the cancer.(claim 38).

There is no support in the disclosure and no description, teaching or guidance that how the claimed compounds as claimed can treat “cancer". No drug so far is known at this time that can treat different cancers by large number of compounds as has been claimed. Examiner would like to refer to a publication by Theodora VoskogLou-Nomokos et al. (Clinical Research, vol. 9, pages 4227-4239, Sept. 15, 2003. See the entire document which clearly explains that treating cancer cannot be predicted (reference enclosed). It is also evident that one drug cannot treat all cancers as claimed.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did ‘little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.’)

Specification in [00400] on page 102 discloses the testing of the compounds for their ability to displace SDF-1 and/or 1-TAC from the CCXCKR2 receptor. Para [00401] and table 1 list the compounds which met the criteria of the method as tested. There is no data to explain the claimed invention. Further paragraph [00403 and [00404] is about assays where MCF c-7 cells were used. There is no guidance/teaching how the "cancer" can be treated. As is now no drug is known which can treat all the type of cancer. The application lacks the description. Applicant had no possession of the claimed invention as has been claimed. Mere indistinct terms (such as “cancer” and “inhibiting the binding of chemokines I-TAC and/or SDF-1 to a CCXCKR2 receptor”, used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice…. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which

features constitute a substantial portion of the genus. See Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

Here, the specification does not provide a reasonably representative disclosure of useful [cancer, or inhibiting the binding of chemokines I-TAC and/or SDF-1 to a CCXCKR2 receptor] generally, a potentially huge genus inclusive of many different compounds having different functions. Since no universal cure for cancer has been developed, it follows that there is no correlation between the assays relied upon by applicants and the ability to treat all cancers. Thus, those assays are not sufficient to enable such claims.

It appears that Applicant had no possession at the time this application was filed of claimed subject matter. The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See In re Kaslow, 707 F 2d 1366, 1375 (Fed. Cir. 1983).
Applicant is kindly requested to explain the issue. In the present case Applicant has no possession for the claimed subject matter. Further formula I covers large number of compounds to treat cancer. At the time invention was filed applicant has no possession of the invention as claimed.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech,* 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).
Further, in the art of clinical oncology, no compound has yet shown clinical efficacy against every type of cancer. Different agents are used for different forms of cancer and no single agent is listed as a treatment of every single type of cancer.

Applicant has provided no evidence, which incontrovertibly demonstrates that the tests set forth in the instant specification are art-recognized, reliable predictors of successful treatable, in vivo, of all cancers. The worker of ordinary skill in the art would not be able to practice the instantly claimed method, since no description is found of an actual method wherein a cancer in a host is treated. Applicants fail to fulfill the requirement of 35 U.S.C. 112, first paragraph, by failing to provide an adequate written description of how to treat all cancers in a single host.

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").
See MPEP 2163.06.

Claim Rejections - 35 USC § 112 (2)

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-7, 14, 15, 19-28 and 30-33 and 35-38 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply:

3. It is unclear what is intended by "modulator" in claims

4. Some compounds not deleted from claim 30 which are clearly non elected invention. The structures are not cancelled in some instances which is consistent to claim 30. All the compounds should be deleted the same way. Some are cancelled by numbers and in some cases structures are deleted.

Double Patenting Rejection

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-7, 14, 15, 19-28, 30-33 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-26 of copending Application No11/478,456. Claims of copending application are drawn to compounds containing a 5-membered ring containing one nitrogen as Z group (which is the elected invention). Same invention has been claimed in present application. Applicant's elected invention is the same as claimed subject matter of copending application.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Response to Remarks

Claims 1-7, 14, 15, 19-28, 30-33 and 35-38 are pending. Amendments are entered. Examiner disagree with the Applicants that claims now claims 1-7, 10, 12, 14, 15, 19-28 and 30-33 are pending (5th line from bottom of the page 17 of remarks). In 3rd paragraph on the same page Applicant say that claims 10-13 were previously cancelled. When claims 10-13 were cancelled than claims 10 and 12 should not be included in pending claims as is in the remarks. Applicants argument are found persuasive therefore double patenting rejection over 11/202,961 now US Patent 7,417,062. Applicants' arguments, filed 12/22/2008, have been fully considered. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the

complete set presently being applied to the instant application. A restriction requirement has been mailed on 11/14/2008 in 11/478,456.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612